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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/817,396	03/26/2001	Hylar L. Friedman	PC10819AMEB	9168
7590 02/02/2004			EXAMINER	
Gregg C. Benson Pfizer Inc. Patent Department, MS 4159 Eastern Point Road Groton, CT 06340			COLE, MONIQUE T	
			ART UNIT	PAPER NUMBER
			1743	
DATE MAILED: 02/02/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/817,396

Applicant(s)

FRIEDMAN ET AL.

Examiner

Monique T. Cole

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 3, 4, 5, 6 & 7 are rejected under 35 U.S.C. 102(b) as being anticipated by abstract of Xie et al. "*Evidence for the Effect of Gender on Activity of (S)-mephenytoin 4'-hydroxylase (CYP2C19) in a Chinese Population*" (herein referred to as "Xie").

Xie teaches subjects that are given 1 100mg tablet of racemic mephenytoin after emptying their urinary bladders. Amounts of (S) and (R) mephenytoin excreted in the post-dose 0-8 h urine collection were determined. From all subjects, metabolic phenotype was determined and DNA was extracted from their blood for genotyping.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Xie in view of USP 5,710,009 to Fitzpatrick (herein referred to as "Fitzpatrick").

Xie teaches the invention substantially as claimed with the exception of expressly teaching that mephenytoin may be detected in a saliva sample. However, Fitzpatrick teaches that it is well known to test for metabolites in serum, saliva or urine (col. 18, lines 19-26). Thus, it would have been obvious to one having ordinary skill in the art to modify Xie by using any of these body fluids to test for mephenytoin with the expectation of achieving reliable results.

Response to Arguments

6. Applicant's arguments filed 10/14/2003 have been fully considered but they are not persuasive.

The crux of Applicant's argument concerning the rejection of claims 1, 3, 4, 5, 6 and 7 as being anticipated by Xie appears to be that the Xie reference teaches an "unwieldy" method for large numbers of patients. Moreover, *"if Xie were used to screen a large number of patients, urine would have to be collected for 0-8 hours after the racemic mephenytoin was administered, which is a long collection time, for a large number of patients."*

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However, since the Xie reference teaches a collection range of from 0 hours to 8 hours, Applicant's argument does not seem sound. The Xie reference reads on any collection time between 0-8 hours including 2 hours as recited in the instant claims. As Applicant as kindly pointed out, in the pending application at page 5, Example 1, a plasma sample was tested at any time between 3 to 8 hours to discriminate between extensive and poor metabolizers. Thus, for the above reason, the 102(b) rejection over Xie stands.

With respect to the rejection of claim 2 as being obvious by Xie and Fitzpatrick, Applicant has argued that one of ordinary skill in the art would not necessarily expect to detect mephenytoin in a saliva sample and that the Fitzpatrick reference does not cure the deficiency of the Xie reference on this point. However, it is the Examiner's position, that the Fitzpatrick reference does not qualify the statement by saying that only certain metabolites can be found in various bodily samples. Thus, the Fitzpatrick reference would still constitute a teaching that various metabolites can be detected in serum, saliva or urine. See also Fitzpatrick col. 1, lines 32-36, where it is taught, "commercial interest has centered on medical diagnostic applications for a wide variety of analytes in biological fluids such as blood saliva and urine." Thus, for the above reasons, Applicant's instant claim remains rejected by the combination of Xie and Fitzpatrick.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monique T. Cole whose telephone number is 571-272-1255. The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0661.

Monique T. Cole
Examiner
Art Unit 1743

MC MC